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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,791	11/13/2003	Roberto Romero	4239-67284-01	8756

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EXAMINER

LUM, LEON YUN BON

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/713,791

Applicant(s)

ROMERO ET AL.

Examiner

Leon Y Lum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-82 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-82 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-16, 33-35, and 37-38, drawn to a diagnostic assay, classified in class 435, subclass 4.
  - II. Claims 39-47, drawn to a method for qualifying the risk of preterm delivery, classified in class 436, subclass 173.
  - III. Claims 48-81, drawn to a method of identifying a subject at risk for a pre-term complication, classified in class 435, subclass 973.
  - IV. Claims 17-32, 36, and 82, drawn to a kit for detecting the presence of at least one biomarker, classified in class 422, subclass 68.1.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and different functions. Group I is a method that includes the limitation of mixing an absorbent that binds at least one biomarker associated with intra-amniotic inflammation with a sample

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of amniotic fluid, which is not a limitation in Group II. Group II includes the limitation of providing a spectrum generated by subjected a sample of amniotic fluid from said subject to mass spectroscopic analysis, which is not a limitation in Group I.

Therefore, Groups I and II have different modes of operation and different functions that distinguish them as unrelated inventions.

3. Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and different functions. Group I includes the limitation of monitoring a mixture for binding between a biomarker and an adsorbent for detecting the presence of at least one biomarker indicative of intra-amniotic inflammation, which is not a limitation in Group III. Group III includes the limitation of defensin, BPI, and calprotectin biomarkers for identifying a subject at risk for a pre-term complication, which is not a limitation in Group I.

Therefore, Groups I and III have different modes of operation and different functions that distinguish them as unrelated inventions.

4. Inventions I and IV are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP §

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806.05(e)). In this case the apparatus as claimed can be used to practice the materially different process of liquid purification by binding specific analytes and heating the adsorbent to destroy the bound analytes.

5. Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and different functions. Group II is a method that includes the limitation of providing a spectrum generated by subjected a sample of amniotic fluid from said subject to mass spectroscopic analysis, which is not a limitation in Group III. Group III includes the limitation of defensin, BPI, and calprotectin biomarkers, which is not a limitation in Group II.

Therefore, Groups II and III have different modes of operation and different functions that distinguish them as unrelated inventions.

6. Inventions II and IV are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice the materially

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different process of liquid purification by binding specific analytes and heating the adsorbent to destroy the bound analytes.

This relationship also applies to Groups III and IV.

7. Because these inventions are distinct for the reasons given above and the search required for each of Groups is not required for the other Groups, restriction for examination purposes as indicated is proper.

Group I requires a search in databases for mixing of a biomarker and an adsorbent, which is not a search required for Groups II-III. Group II requires searching in databases for mass spectroscopic analysis, which is not a required search for Groups I and III-IV. Group III requires searching in databases for defensin, calprotectin, and BPI, which are not required searches for Groups I-II and IV. Group IV requires searching in databases for kits that include instructions and adsorbents, which is not required for Groups I-III.

8. In the event that Applicant elects Group III, the following species election applies:

This application contains claims directed to the following patentably distinct species of the claimed invention:

- a. Species: type of preterm complication (for Group III only):
  - i. Preterm parturition, claim 63
  - ii. Preterm PROM, claim 64

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iii. Intra-amniotic inflammation, claim 65

iv. MIAC, claims 66 and 74-78.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Currently, claims 48-62, 67-73, and 79-81 (for Group III) are generic.

Claims 63-66 and 74-78 (for Group III) are subject to species election.

For example, if Applicant elects Group III, species iv, claims 48-62 and 66-81 comprise the election.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

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are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. A telephone call was made to Kevin Hayes on 05 January 2005 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).



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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leon Y Lum  
Patent Examiner  
Art Unit 1641



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